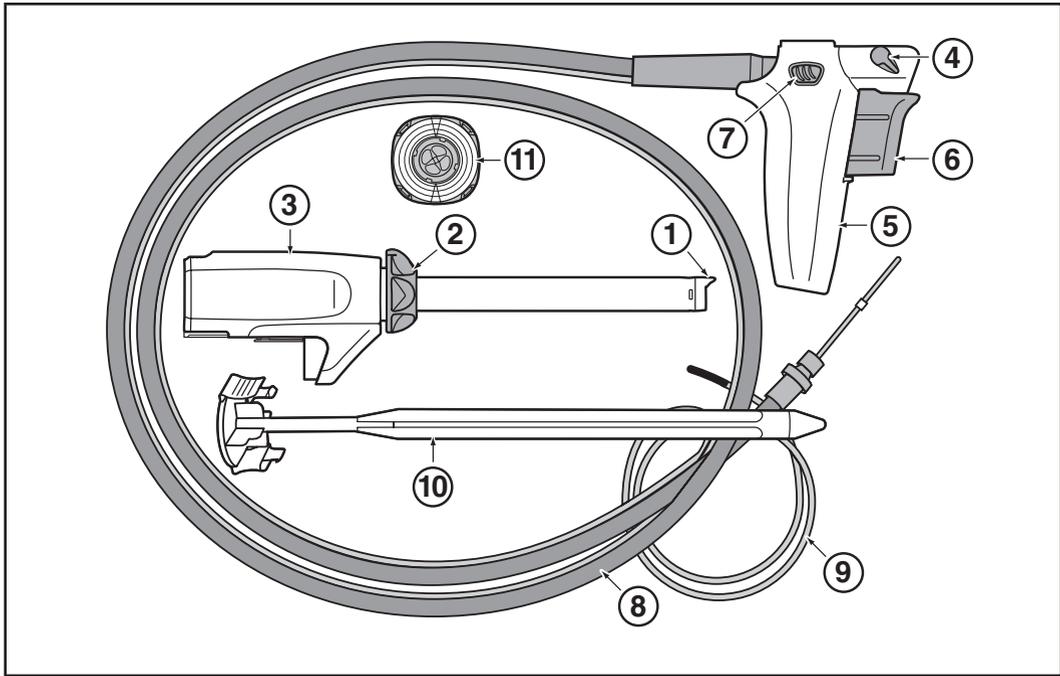


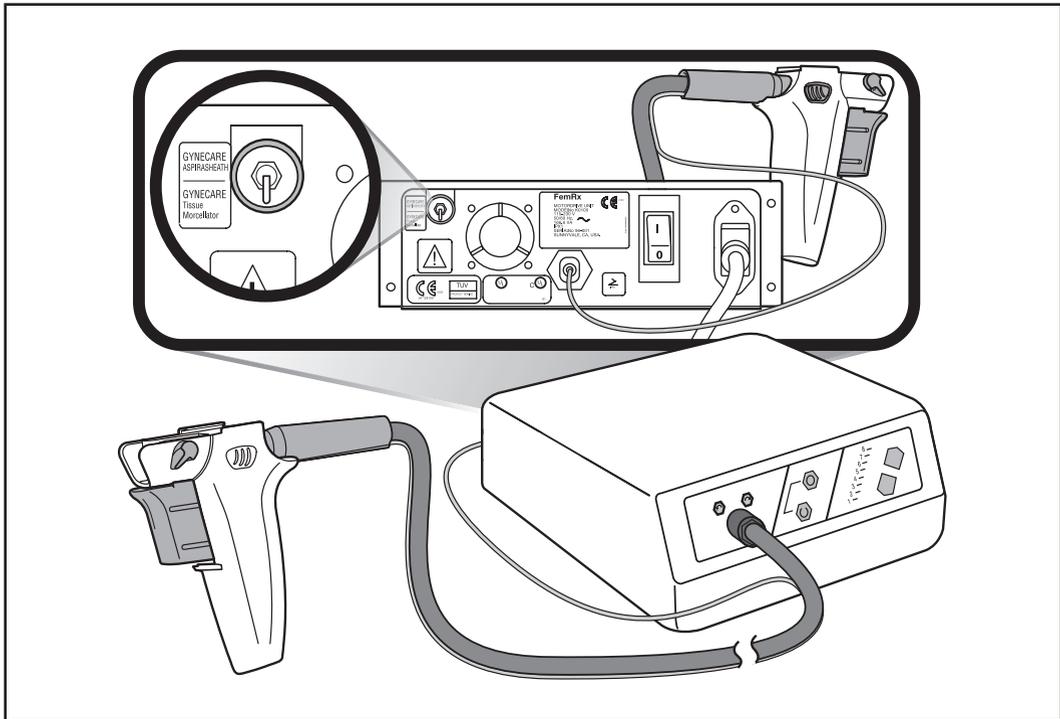
Gynecare Morcellex™

Tissue Morcellator

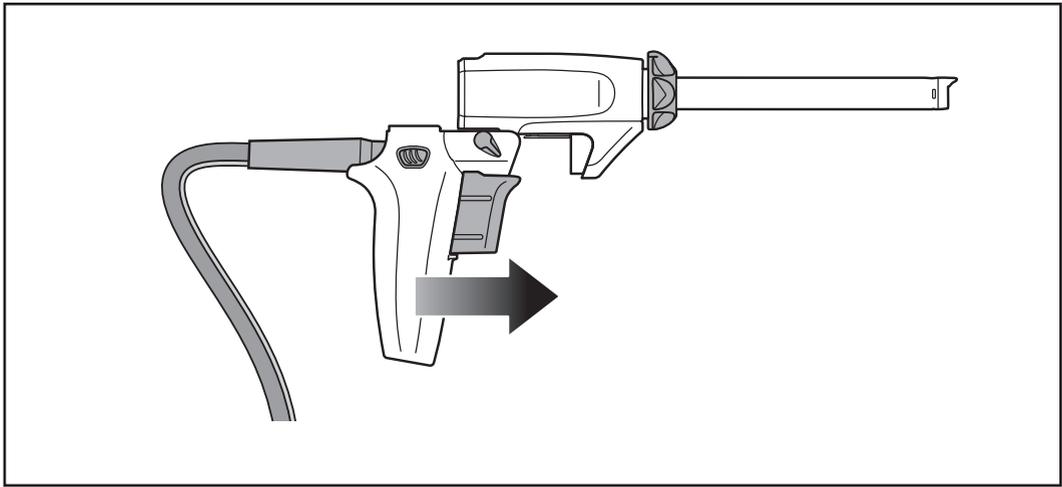
GYNECARE MORCELLEX™ vævsmorcellator
GYNECARE MORCELLEX™ weefselmorcellator
GYNECARE MORCELLEX™ -kudospaloittelija
Morcellateur de tissus GYNECARE MORCELLEX™
GYNECARE MORCELLEX™ Gewebezerstückler
Morcellatore di tessuto GYNECARE MORCELLEX™
Morcelador de tecidos GYNECARE MORCELLEX™
Morcelador de tejido GYNECARE MORCELLEX™
GYNECARE MORCELLEX™ vävnadsmorcellator
Εργαλείο κατάτμησης ιστών GYNECARE MORCELLEX™
Morcelátor tkáně GYNECARE MORCELLEX™
GYNECARE MORCELLEX™ koemorsellaator
GYNECARE MORCELLEX™ szövetaprító eszköz
GYNECARE MORCELLEX™ audu morcelators
GYNECARE MORCELLEX™ audinių smulkintuvas
Morcelator tkankowy GYNECARE MORCELLEX™
Морцеллятор GYNECARE MORCELLEX™
Odstraňovač tkaniva GYNECARE MORCELLEX™
GYNECARE MORCELLEX™ doku morselatörü



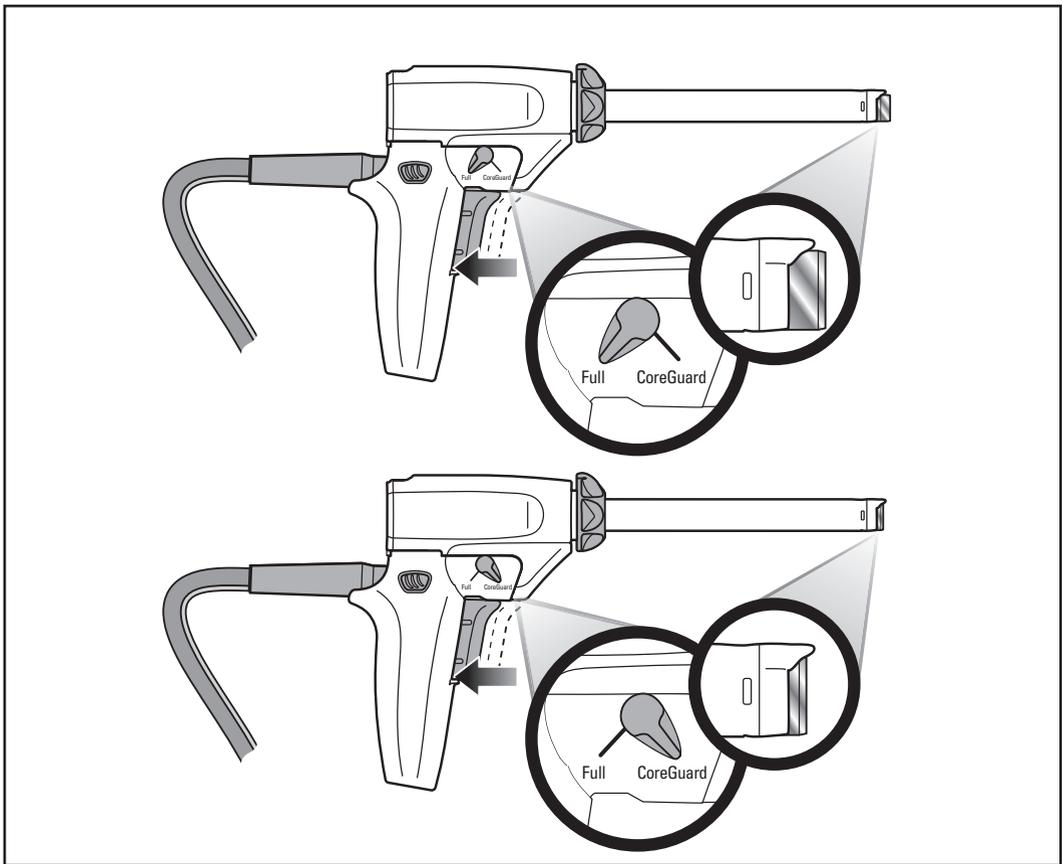
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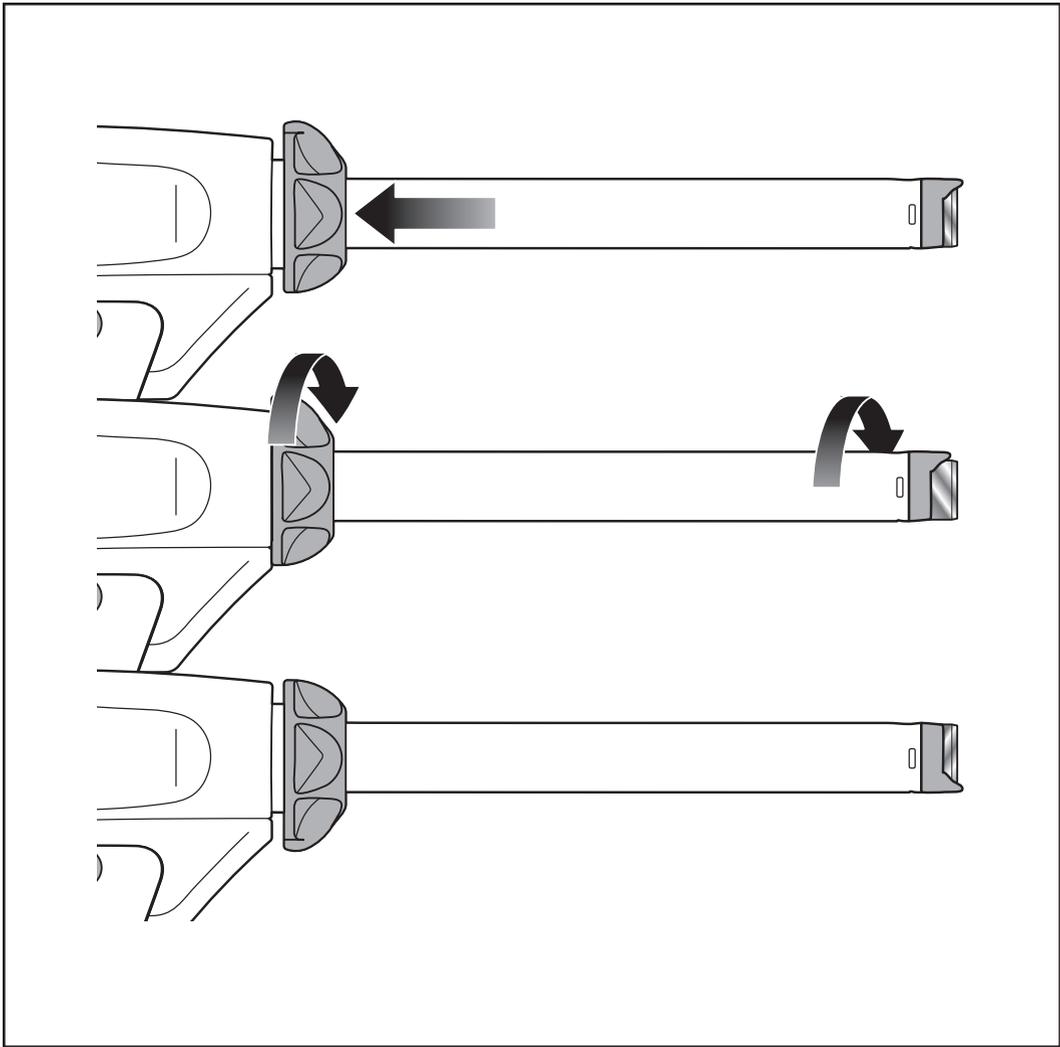
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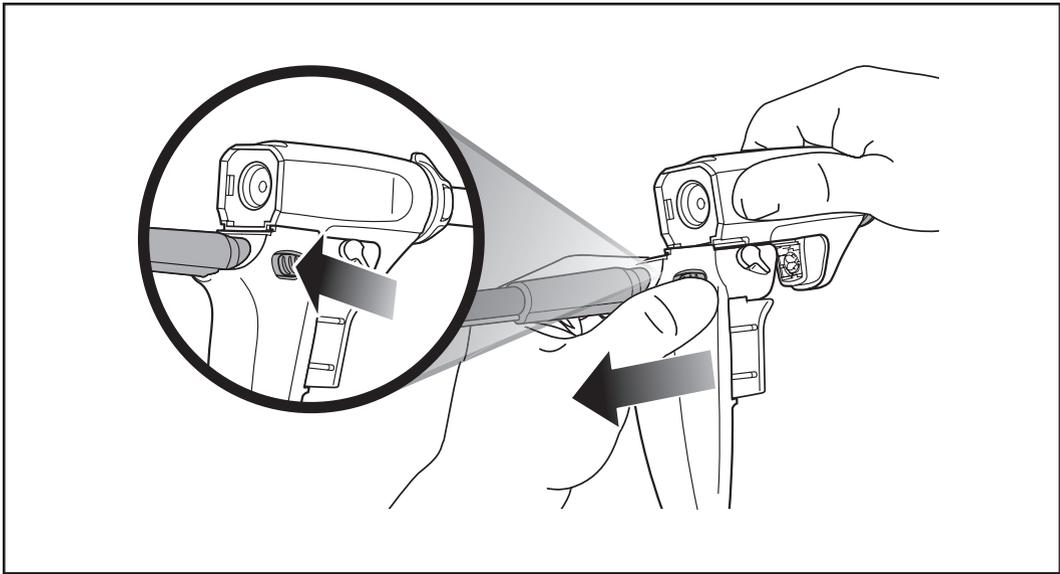
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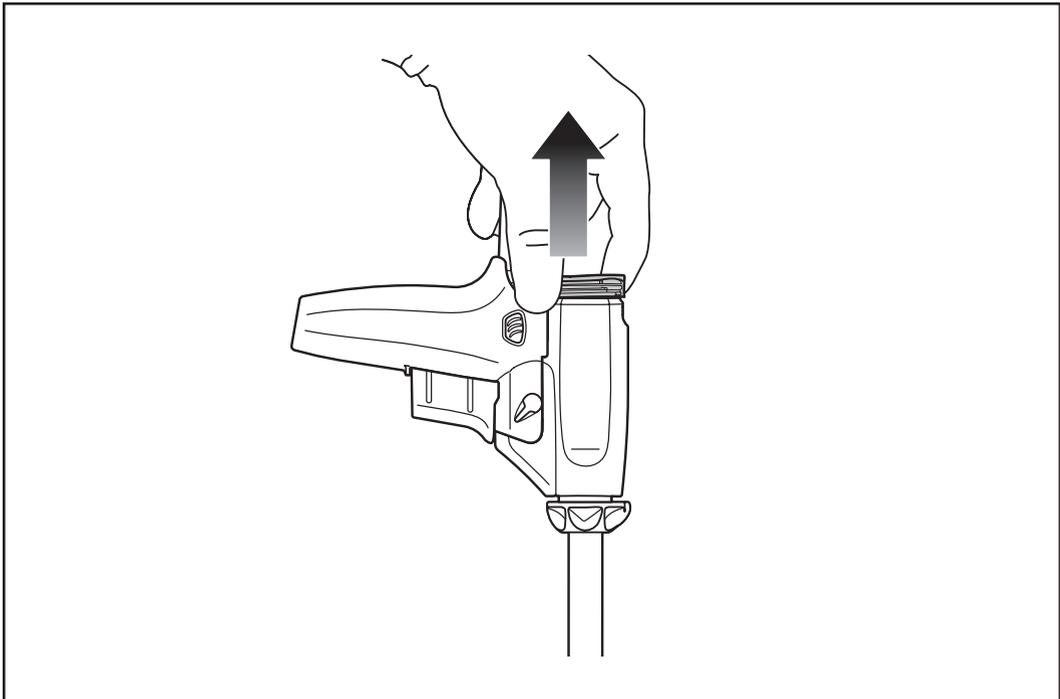
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6



7



Please read all information carefully.

Rx only

DESCRIPTION

The GYNECARE MORCELLEX™ Tissue Morcellator is a single-patient-use device. The device is inserted into the patient with the use of the provided single-patient-use Obturator. The device allows tissue to be grasped with a standard grasping instrument extended through its central lumen. The tissue can be drawn up inside the device's central lumen into the inner stationary sheath as the exposed blade cuts the tissue. The physician can activate the GYNECARE MORCELLEX™ Tissue Morcellator via a foot pedal or via the dual-function Blade Guard/Activation Trigger on the device's Detachable Handle. The device can operate in either coring or peeling mode based on the degree of exposure of the blade and placement of the rotatable Coreguard. The device is packaged with a single-patient-use reducer cap to allow the optional use of a 5mm instrument. See Figure 1.

The following features are highlighted in Figure 1.

- ① Coreguard
- ② Coreguard Rotating Knob
- ③ Blade Housing Assembly
- ④ Blade Position Selector
- ⑤ Detachable Handle
- ⑥ Blade Guard / Activation Trigger
- ⑦ Handle Detachment Button
- ⑧ Flexible Drive Cable
- ⑨ Detachable Handle Air Tube
- ⑩ Obturator
- ⑪ Reducer Cap

The variable-speed, reversible GYNECARE® Motor Drive Unit (MDU) drives the rotation of the blade of the GYNECARE MORCELLEX™ Tissue Morcellator at a controlled speed and torque after connection of the device to the MDU via the Flexible Drive Cable. An operating room staff member outside of the sterile field controls the direction and speed of rotation on the MDU.

INTENDED USE

The GYNECARE MORCELLEX™ Tissue Morcellator is intended for gynecologic, urologic and general surgical endoscopic use by trained professionals in hospital environments and ambulatory surgery centers.

INDICATIONS

The GYNECARE MORCELLEX™ Tissue Morcellator is indicated for cutting, coring and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures and laparoscopic gynecologic procedures.

CONTRAINDICATIONS

The GYNECARE MORCELLEX™ Tissue Morcellator is contraindicated for use on vascularized tissue or as a dissecting tool. All target tissues and organs must be devascularized and dissected before morcellation.

WARNINGS

- Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and may have an adverse effect on procedural outcomes.
- The GYNECARE MORCELLEX™ Tissue Morcellator is a precision instrument that must be handled with care by well-trained and knowledgeable professionals. Carefully inspect the device and all associated equipment, instrumentation and cabling for damage prior to use. DO NOT attempt to operate this instrument if any damage is observed. Contact 1-877-ETHICON for replacement of a damaged device.
- Use only the GYNECARE® Motor Drive Unit (MDU) to connect to the GYNECARE MORCELLEX™ Tissue Morcellator. Use of any other drive mechanism may result in failure of the device to operate or lead to patient or physician injury.
- To prevent accidental injuries to the abdominal wall or similar structure, the tissue to be morcellated should be completely exposed before applying the device. In addition, it is recommended that a second pair of grasping forceps or a fixation instrument be used to prevent large pieces of tissue from uncontrollably moving. Unintended movement of the device can cause significant injury.
- DO NOT attempt to sharpen or modify the blade of the device. Bent or distorted blades can result in patient or physician injury and equipment damage.
- Use caution when introducing or removing instruments to prevent inadvertent damage to device seals. Special care should be used when inserting sharp or angled-edged endoscopic instruments to prevent tearing of the seals.

PRECAUTIONS

- The physician must be thoroughly familiar with and carefully follow all manufacturer's instructions pertaining to this device and all associated accessories, equipment and instrumentation.
- As with any endoscopic instrument, procedures performed using the GYNECARE MORCELLEX™ Tissue Morcellator require adequate knowledge, training and preparation on the part of the physician.
- The blade should be completely covered during insertion and removal of the instrument. Exercise care when inserting or removing the instrument. Insertion and removal of the instrument should be performed under direct visualization at all times.
- This device is intended for single patient use. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users.
- CAUTION: Do not place the exposed blade in contact with tissue that is not intended to be morcellated. Exercise caution while manipulating the device at all times.
- CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the physician considers to be potentially harmful when disseminated in a body cavity. As morcellation may affect endometrial pathologic examination, preoperative evaluation of the endometrium should be considered. Should malignancy be identified, use of the GYNECARE MORCELLEX™ Tissue Morcellator may lead to dissemination of malignant tissue.

TECHNICAL SPECIFICATIONS

Specifications

Functional:	Speed Range	125 to 1000 rpm
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INSTRUCTIONS FOR USE

Placement of the Blade Housing Assembly into the Patient

1. Insert the Obturator through the central lumen of the Blade Housing Assembly.
2. Align the latches on the Obturator with a latch slot on top of the Blade Housing Assembly.
3. Press the Obturator into place by applying pressure. An audible "click" is heard when the obturator is securely placed into the Blade Housing Assembly.
4. Insert this assembly under direct visualization through an adequately sized incision.
5. After positioning the Blade Housing Assembly of the GYNECARE MORCELLEX™ Tissue Morcellator, remove the Obturator by squeezing the latches on the Obturator inward and pulling the obturator out from the Blade Housing Assembly.
6. The Blade Housing Assembly may be used as an operative port until the time that tissue morcellation is required.

Connection of the Flexible Drive Cable to the MDU

1. Locate the Drive Cable Receptacle on the front of the MDU and press down the metal tab until it locks into place.
2. Carefully insert the free end of the Flexible Drive Cable into the Drive Cable Receptacle on the MDU. Rotate the cable end from side-to-side until it engages.
3. Press in the surrounding fitting firmly until the metal tab releases and springs upward into place.
4. Ensure that the mode switch, located on the back panel of the MDU, is set in the down position to the "Morcellator" mode. See Figure 2.
5. If the operator wishes to activate the motor via the foot pedal the operating room staff member should connect the small tubing from the foot pedal (Foot Pedal Air Tube) to the back of the MDU. If the operator wishes to activate the motor via the Activation Trigger on the Detachable Handle, the operating room staff member should connect the small tubing from the Detachable Handle cable (Detachable Handle Air Tube) to the back of the MDU. See Figure 2.

Operation of the GYNECARE MORCELLEX™ Tissue Morcellator with the MDU

1. The blade's rotational speed may be increased and decreased in increments of 42 rpm by pressing on the upward-pointing and downward-pointing yellow membrane switches on the front of the MDU. The change in the number and/or intensity of the illuminated lights on the front panel of the MDU indicates that speed has been increased or decreased.
2. DO NOT attempt to sharply bend the Flexible Drive Cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the MDU to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the MDU and the GYNECARE MORCELLEX™ Tissue Morcellator to allow the drive cable to hang in a large arc with no bends, loops or kinks.
3. If it appears that the blade has stopped rotating during a procedure, check to ensure that all connections to the GYNECARE MORCELLEX™ Tissue Morcellator and MDU (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.
4. If the Flexible Drive Cable wraps up and stalls the motor, press the red stop button, reverse the direction of blade rotation with the appropriate directional arrow button, and intermittently run the motor in one second intervals until the drive cable unwraps and hangs freely with no loops.
5. The MDU contains an internal switch that automatically shuts the unit off if it overheats. In this event, switch the main power switch (on the back of the MDU unit) to OFF and allow the unit to cool for several seconds before restarting.

Tissue Morcellation with the GYNECARE MORCELLEX™ Tissue Morcellator

1. When ready to morcellate tissue, slide the Detachable Handle into the Blade Housing Assembly until it seats firmly. Do not press the Activation Trigger during handle assembly. See Figure 3.
2. Insert a 10mm claw forceps, tenaculum or similar instrument through the central lumen of the device and into the abdomen.
3. Grasp the tissue to be extracted and pull the specimen up to the distal end of the GYNECARE MORCELLEX™ Tissue Morcellator.
4. Set the desired amount of blade exposure by setting the Blade Position Selector to the "Fully Exposed" [Full] setting to morcellate via the coring technique or the "Coreguard" [CoreGuard] setting to morcellate via the peeling technique. See Figure 4.
5. Partially depress the Blade Guard/Activation Trigger on the Detachable Handle to expose the blade. See Figure 4.
6. The Blade may be then activated via (a) the Activation Trigger on the Detachable Handle or (b) the Foot Pedal.
 - a. If the hand activation of blade rotation is desired confirm that the Detachable Handle Air Tube is connected to the back of the MDU. Then fully depress and hold the Activation Trigger on the Detachable Handle to activate the MDU and start the rotation of the blade.
 - b. If foot pedal activation is desired confirm that Foot Pedal Air Tube is connected to the back of the MDU, depress the foot pedal to activate the MDU and start the rotation of the blade. When the foot pedal tube is connected to the MDU, further depression of the Blade Guard/Activation Trigger will have no effect once the blade is exposed.
7. With the blade exposed and rotating, pull the tissue through the device. In order to prevent injury, the tissue to be morcellated should be completely exposed and freed from surrounding tissue before attempting to extract it through the instrument. It is recommended that an assistant with a second pair of grasping forceps or other fixation instrument help control tissue movement.
8. If desired, the location of the Coreguard can be changed to any of its twelve positions by pulling the Coreguard rotating knob towards the proximal end of the Blade Housing Assembly and then rotating it to locate the Coreguard at the desired location. See Figure 5.
9. When morcellation of the tissue is complete, fully release the Blade Guard/Activation Trigger to stop and cover the blade. If using the foot pedal to activate the blade, release the foot pedal to stop the rotation of the blade and then fully release the Blade/Guard/Activation Trigger to cover the blade.
10. To separate the Detachable Handle from the Blade Housing Assembly press the handle detachment buttons and remove the Detachable Handle from the Blade Housing Assembly leaving the Blade Housing Assembly in place to serve as an operative port for any additional instruments required to complete the laparoscopic procedure. See Figure 6.

Use of Reducer Cap with Blade Housing Assembly

1. Using sterile technique, remove the Reducer Cap from the package. To avoid damage do not flip the device into the sterile field.
2. Align the latches on the Reducer Cap with a latch slot on top of the Blade Housing Assembly.
3. Press the Reducer Cap into place by applying pressure. An audible "click" is heard when the cap is securely placed on the Blade Housing Assembly.
4. Insert instruments into the instrument port. The Reducer Cap can accept 5mm-12mm instruments through its self-adjusting seal without the need for manual adjustment or the loss of pneumoperitoneum.
5. Remove the Reducer Cap from the Blade Housing Assembly by pulling or pushing up on the side of the Reducer Cap. See Figure 7.

NOTE: The Reducer Cap should be removed from the Blade Housing Assembly prior to attaching or detaching the Detachable Handle.

STORAGE

The GYNECARE MORCELLEX™ Tissue Morcellator should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.

STERILITY

The GYNECARE MORCELLEX™ Tissue Morcellator is sterilized by gamma irradiation. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

DISPOSAL

For proper disposal of the GYNECARE MORCELLEX™ Tissue Morcellator, insert the Obturator through the lumen of the Blade Housing Assembly. Then dispose of the device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

Symbols Used on Labeling

 0086 CE-mark and Identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC	 Manufacturer	 PHT DEHP Contains or Presence of Phthalates
 Batch number	 Do not reuse	 Rx only CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner
 Use by — Year and Month	 Do not resterilize	
 Defibrillator-proof type BF equipment	 See Instructions for Use	
	 Method of Sterilization — Cobalt	